BOARD OF VOCATIONAL NURSING AND PSYCHIATRIC TECHNICIANS

SUPPLEMENT TO FINAL STATEMENT OF REASONS

Vocational Nursing Regulations

Sections 2542, 2542.1, 2547, and 2547.1

The following changes have been made to the text of the regulation**:**

Section 2542.1 subparagraph (b)(2), and section 2547.1 subparagraph (b)(2) have been amended by adding language explaining that the method of specialized instruction in proper procedure from a registered nurse or a licensed physician and the demonstration required by the regulation, shall be set forth in the standardized procedures of the facility. Section 2542.1 subparagraph (5), and section 2547.1 subparagraph (5) have been amended by adding language explaining that the definition of "immediate vicinity" shall be set forth in the standardized procedures of the facility.

Amendments to Informative Digest:

The Board updated the Informative Digest to reflect the reason for the resubmission of the regulation.

Amendments to Initial Statement of Reasons:

The Initial Statement of Reasons is part of the rulemaking file and is updated as follows:

The Board determined that sufficient new material exists to address OAL's concerns regarding the evolution of nursing practice in a resubmission of the regulations. The Board published a list of the additional material relied upon in a notice of *Availability of Documents Added to Rulemaking File* on June 5, 2002.

To address OAL's concern regarding the clarity of the term "immediate vicinity," the Board published a notice of *Availability of Second Modified Text* on June 5, 2002.

Small Business Determination:

The Board has no amendments to the Small Business Determination.

Consideration of Alternatives:

The Board has determined that no reasonable alternative considered by the Board or that has otherwise been brought to its attention would be more effective in carrying out the purpose of the proposed regulation, or would be less burden some to affected private persons than the proposed action.

Determinations:

The Board has determined that the proposed regulatory action does not impose a mandate on local agencies or school districts, which would require reimbursement pursuant to Part 7 (commencing with section 17500) of Division 4 of the Government Code (GC).

BOARD RESPONSE TO OFFICE OF ADMINISTRATIVE LAW'S DECISION

The Office of Administrative Law (OAL) based its disapproval of the regulatory proposal on reasons that the proposal did not meet standards of (I.) Authority/Consistency, and (II.) Clarity; and (III.) that the proposal did not meet a procedural requirement ensuring effective review due to missing or defective documents.

OAL's concerns relative to these three items are addressed individually as follows:

I. AUTHORITY/CONSISTENCY

"The proposed regulations enlarge the scope of practice of the LVN and appear to be inconsistent with the Vocational Nursing Practice Act."

Government Code (GC) section 11342.1 provides that each regulation adopted, to be effective, shall be within the scope of authority conferred and in accordance with standards prescribed by other provisions of law. OAL explained that an administrative agency does not have the authority to exercise its rulemaking power to alter, extend, limit, or enlarge the provisions of the statute that it administers. Further, OAL questioned whether the Legislature envisioned the definition of intravenous fluids to include medications such as anticoalgulants or antibiotics. OAL stated that "Although the matter is not free from doubt, it appears to us that in ordinary medical terminology, use of the term "intravenous fluids does not include medication…". OAL further indicated that since the Vocational Nursing Act has no language which expressly recognizes that [vocational] nursing is a dynamic field, the practice of which is continually evolving, it is not be afforded the same kind of flexibility in the interpretation of the scope of practice as registered nurses. OAL acknowledged in its decision that modern medical technology has advanced considerably since B&P Code section 2860.5 was last amended in 1974. In so doing, OAL remarked:

> "Old definitions and understandings may need to be changed if medical and nursing practices have evolved to the point where professionals in the field would consider such medications as an integral component or ingredient in intravenous fluids."

In its decision, OAL stated that if the Board can supplement the record with facts, studies, expert opinion or other information that tends to show that nursing practice has evolved to the point where professionals in the field consider medications an integral component or ingredient in intravenous (IV) fluids, the regulations could be resubmitted for further OAL review and consideration.

BOARD RESPONSE:

The Board respectfully requests that OAL again review whether the Board has exceeded its authority in adopting a regulation that expands the scope of IV therapy practice of licensed vocational nurses (LVN), and whether the Board's IV therapy practice interpretation as reflected in its proposed regulation is based upon a reasonable interpretation of B&P Code section 2860.5.

The Vocational Nursing Practice Act (B&P Code section 2859) permits LVNs to perform vocational nursing services under the direction of a licensed physician or registered professional nurse. As clarified in title 16, CCR section 2518.5 of the Vocational Nursing Regulations, such services include, but are not limited to, medication administration in accordance with a licensed physician's order that is patient specific, the performance of basic assessment (data collection), participation in planning care, execution of interventions in accordance with the care plan or treatment plan, and contributing to evaluation of individualized interventions related to the care plan or treatment plan as described section 2518.5.

Additionally, B&P Code section 2860.5(c)(2) permits the infusion of IV fluids by LVNs who are Board-certified in IV therapy provided that the procedure is performed in an organized health care system in accordance with written standardized procedures adopted by the organized health care system. These standardized procedure provisions for LVNs that are available for LVNs solely with respect to IV therapy, parallel the standardized procedure provisions of B&P Code section 2725 that are available to RNs on a much broader scale.

Read together, the laws discussed above authorize LVNs who are Board-certified in IV therapy to administer a range of IV fluids that include medications provided that the administration is performed by an appropriately trained LVN in an organized health care system in accordance with written standardized procedures adopted by the organized health care system. To ensure consumer safety, the Board is further clarifying and limiting those circumstances by these regulations.

A June 4, 2002, legal opinion answers the question of whether the Board has the authority to amend its regulations to permit LVNs, with specialized certifications and under specific circumstances, to intravenously administer Category I and Category II fluids. Further, the opinion addresses questions of consistency with the Vocational Nursing Practice Act, and Legislative intent. A copy of the opinion, a legal memorandum entitled *Authority for Intravenous Therapy Regulatory Amendment*, is included in the addendum to the rulemaking file.

On the matter of usage of the term "intravenous fluid," although OAL questioned whether in ordinary medical terminology, use of the term intravenous fluids encompasses medications, the following two examples indicate that hypodermic injections of medications in fluid form, intravenously, is clearly contemplated by section 2860.5:

1. Section 2860.5(a) of the Vocational Nursing Practice Act states, LVNs may "[a]dminister **medications** by **hypodermic injection**." Taber's Cyclopedic Medical Dictionary, 2001 edition, defines "hypodermic" as "Under or inserted under the skin, as a hypodermic injection. It may be given subcutaneously (under the skin), intracutaneously (into the skin), intramuscularly (into a muscle), intraspinally (into the spinal canal), or ***intravascularly*** **(into a vein or artery**)." [Emphasis added.]

2. The American Heritage Dictionary defines "hypodermic injection" as "[a] subcutaneous, intracutaneous, intramuscular, or **intravenous** injection by means of a hypodermic syringe and needle." [Emphasis added.]

It follows, then, that LVNs are already authorized by subdivision (a) of section 2860.5 to administer medications in fluid form by IV injection. Accordingly, the silence of subdivision (c) of that same section 2860.5, with respect to "medications," most reasonably implies that an organized health care system is not barred from utilizing its LVNs to start and superimpose IV fluids containing certain medications that the facility deems appropriate. Put differently, the Board does not believe that the absence of repetition of the term medications in subdivision (c) of section 2860.5 was intended to bar all IV therapy involving any "medications" from all future LVN practice. One could indeed identify exclusion of that practice as the legislative intent <u>if</u> the Legislature specifically stated that LVNs <u>cannot</u> administer medications in the course of IV therapy. The Legislature did not so state. Although much is made of the omission of certain language just before the bill was passed that would have explicitly authorized this practice, language is often omitted from a bill in order to appease opponents, proponents believing that there is no change in effect of the law by its loss. To assume otherwise in this case is to write a categorical prohibition into a statute that is instead intended to afford to physicians and other health care professionals in an organized health care system significant flexibility in their utilization of LVNs to perform IV therapy under standardized procedures.

OAL indicated that the Vocational Nursing Practice Act, without the extremely broad language comparable to that of B&P Code section 2725, does not have the same kind of flexibility as registered nurses. However, the same flexibility is hardly needed or deserved to find the flexibility needed to conform the Vocational Nursing regulations to currently evolved IV therapy practice – and is actually introducing some limitations thereon. LVNs are simply not RNs nor do they have the same education and training. What is needed is merely flexibility that is consistent with VN competencies, in the specific area of IV therapy practice.

<u>Evolution of Nursing Practice</u>

Sufficient new material exists that demonstrates that medical and nursing practice have evolved such that professionals in the intravenous therapy field now consider medications an integral component or ingredient in IV fluids. This standard, set for the Board by OAL, is ably and concisely responded to by Dr. Thomas Paukert in his comments; he states that definitions have changed over time and IV fluids, as the term is commonly used today, regularly includes fluids which contain medication as a component. The regulation as adopted will provide flexibility to professionals in the field to determine if an LVN is skilled enough to provide IV therapy which contains Category II fluids.

This material is included in the addendum to the rulemaking file (see *Availability of Documents Added to Rulemaking File*). The additional underlying data relied upon by the Board is as follows:

(a.) June 4, 2002, Legal Opinion, Laura Freedman Eidson, Staff Counsel, Legal Affairs Office, Department of Consumer Affairs
(b.) May 30, 2002, Letter from Thomas Paukert, M.D., President, California Dialysis Council
(c.) May 30, 2002, Letter from Rafael Fletes, Jr., M.D., Balboa Nephrology Medical Group,

Inc., San Diego, CA
(d.) May 30, 2002, Letter from Gail A. Frederick, BSN, CNN
(e.) May 22, 2002, Letter from Dr. Harbans Singh, Medical Director, Gambro Healthcare
(f.) May 2002 Survey by the Board of Vocational Nursing and Psychiatric Technicians of 49 State Boards of Nursing
(g.) August 30, 1974, AB 3618 Enrolled Bill Report
(h.) Statutes of California 1974, Chapter 1084
(i.) January/February 1998 Supplement to Journal of Intravenous Nursing – Revised Intravenous Nursing Standards of Practice
(j.) Delegation of Nursing Care Activities, American Nephrology Nurses Association
(k.) Position Statement, The Role of the Licensed Practical Nurse in Dialysis, The Renal Network, Inc.

The contemporary acceptance of the LVN as an active participant in IV therapy is evidenced by opinions submitted by experts in the field of dialysis following the publication of OAL's decision. The Board received a number of letters in support of the regulations that also urged resubmission of the regulations and/or provided expert testimony and a historical perspective of the evolution of nursing practice in dialysis settings. These letters support the Board's conclusion that the evolution of vocational nursing practice ***must*** keep pace with the evolution in technology that over the span of 30 years has brought about dramatic improvement in patient outcomes and increased demand for nursing services and as such are included in the public comment section of the addendum to the rulemaking file.

The contemporary role of the LVN in IV therapy is also evidenced by the results of a survey conducted by the Board in May 2002. In May 2002, the Board surveyed other state boards of nursing to determine which states permit LVNs/ Licensed Practical Nurses (LPNs) to administer IV medications. Forty-four states responded to the survey. All 44 states reported that LVNs/LPTs are permitted to administer a range of IV medications.

The Board also conducted a survey of major professional organizations with respect to the role of LVNs in IV therapy. The survey found that the following organizations support the role of the LVN/LPN in IV therapy:

- The American Nephrology Nurses' Association (ANNA).

  ANNA recognizes that "achievement of favorable patient outcomes is a collaborative effort between nurses, physicians and other personnel." The association supports delegation of tasks related to hemodialysis to LVNs as long as those tasks are within the scope of practice delineated by the board of nursing for the state in which the LVN is practicing.

- The Intravenous Nurses Society (INS).

  In the January/February 1998 *Supplement to Journal of Intravenous Nursing, Revised Intravenous Nursing Standards of Practice*, the INS states, "The intravenous nurse may be an RN or a licensed practical/vocational nurse (LPN/LVN) who has acquired knowledge and skill in intravenous nursing."

- The Renal Network, Inc.

  The Renal Network is a not-for-profit organization which monitors quality of dialysis care. In 1994, the Renal Network issued the following position statement:

  > "The Renal Network, Inc. supports the use of the Licensed Practical Nurse (LPN) in dialysis to perform all of the basic procedures required to provide a hemodialysis and/or peritoneal dialysis treatment plus the ability to initiate and terminate the dialysis process regardless of the access site and to administer specific medications to patients undergoing dialysis, under the direct supervision of a licensed registered nurse or physician."

II. CLARITY

"Proposed language includes the term "immediate vicinity," which is not defined."

OAL found that the proposed regulations did not meet the standard of review for Clarity because neither the Board's governing statutes nor its regulations define the term "immediate vicinity," and without a definition, persons presumed to be directly affected would not understand the meaning of the term. OAL found that the Board had not explained the provision containing the term "immediate vicinity," or its effects in the *Initial* or *Final Statement of Reasons*, or elsewhere in the rulemaking file.

BOARD RESPONSE:

The Board agrees with OAL that directly affected persons may not understand the term "immediate vicinity" as used in the proposal without first defining the term. Proposed sections 2542.1(b)(5) and 2547.1(b)(5) would provide that an LVN may start and superimpose Category II intravenous fluids in hemodialysis, pheresis or blood bank settings under specified conditions, including the condition that a registered nurse or licensed physician is in the immediate vicinity. To ensure that the proposed regulations are clear to those persons directly affected the Board is modifying sections 2542.1(b)(2) and (5), and 2547.1(b)(2) and (5) of the proposed text of the regulations. The modified text explains that the definition of "immediate vicinity" for each facility shall be set forth in the standardized procedures.

Although OAL did not specifically comment on proposed sections 2542.1(b)(2) and 2547.1(b)(2), which would specify that an LVN must receive specialized instruction in proper procedure from a registered nurse or a licensed physician and must demonstrate to a registered nurse or a licensed physician the requisite knowledge, skills and abilities to perform the procedure, the Board is modifying section 2542.1(b)(2), and section 2547.1(b)(2) of the proposed text of the proposal to ensure that the regulations are clear to those persons directly affected. The modified text explains that the method of specialized instruction required by the regulation shall be set forth in the standardized procedures of the facility.

The Board published a 15-day notice of *Availability of Second Modified Text* on June 5, 2002. The public comment period concluded on June 20, 2002. A summary of comments received during the public comment period and the Board's responses are included in Attachment A.

III. MISSING OR DEFECTIVE DOCUMENTS

"The micro-cassette recording included in the rulemaking file is not sufficiently audible and there is no transcript or minutes."

GC section 11347.3(b)(8) provides that the rulemaking file shall include "[a] transcript, recording, or minutes of any public hearing connected with the adoption, amendment, or repeal of regulation." Section 90, title 1 of the CCR further specifies that such information shall accurately reflect all proceedings applicable to the rulemaking action and shall be adequate to ensure effective review of the record by OAL.

OAL found that the rulemaking record contained a micro-cassette tape purported to be a recording of the public hearing of April 17, 2001, but did not contain a corresponding transcript or minutes. The quality of the micro-cassette copy was found to be poor and mostly inaudible, and although the *Final Statement of Reasons* contained summaries and responses to the oral hearing, OAL did not have an opportunity to review them for accuracy and completeness.

BOARD RESPONSE:

In response to OAL's concern regarding the audio quality of the copy of the micro-cassette tape submitted with the initial filing of the proposal, the Board is submitting minutes of the regulatory hearing of April 17, 2001, which are included in the addendum to the rulemaking file.

OTHER CONSIDERATIONS

Although not listed as a ground for disapproval, OAL suggested that proposed sections 2542 and 2547, Definitions, list the defined terms in alphabetical order, as a more reader-friendly format. While the Board agrees that an alphabetical listing of the definitions may be more user-friendly to some readers of the regulations, the Board believes that the list of definitions as currently ordered provides the greatest degree of clarity for those persons directly affected by the proposal. However, the Board intends to review all of its regulations for consistency in the near future and may, at that time, consider using an alphabetical format for lists of definitions.

SUMMARY OF COMMENTS AND BOARD RESPONSES

Following the publication of the Office of Administrative Law's (OAL) *Decision of Disapproval*, the Board received 19 letters in support of the regulations. Some of these letters urged resubmission of the regulations and/or provided expert testimony and a historical perspective of the evolution of nursing practice in dialysis settings. As such, these letters are included in the addendum to the rulemaking file.

During the 15-day public comment period for the second modified text, June 5 through June 20, 2002, the Board received 184 letters in support of the regulations. A number of letters expressed general support for the regulations, and a number of letters expressed support for the most recent modifications. Supporters include physicians; administrators and staff from dialysis and nephrology clinics throughout California; and individual nurses.

During the comment period, the Board received 80 letters in opposition to the regulations. A number of letters expressed general opposition to the Board's proposal, and a number of letters expressed opposition to the most recent modifications. A number of letters contain comment to the effect that the additional documents do not meet a necessary standard for further review and consideration by the OAL. Opponents include the California Nurses Association; the American Nurses Association; the California Department of Health Services; the Board of Registered Nursing; and individual nurses.

The following table delineates the comment included in the addendum to the rulemaking file:

PUBLIC COMMENT	
POSITION	**NUMBER OF COMMENTS RECEIVED**
SUPPORT - following OAL's Decision	**19 letters**
SUPPORT – 15-day comment period	**184 letters comprising 187 signatures**
OPPOSITION – 15-day comment period	**80 letters comprising 129 signatures**
Total Comments Included in Resubmission	**283**

Attachment A, *Intravenous Therapy Regulations, Summary and Board Responses to Comments, June 5, 2002, through June 20, 2002*, summarizes comments representative of those submitted following the publication of OAL's *Decision of Disapproval*; and during the 15-day public comment period, June 5 through June 20, 2002, in aggregate categories (1) in support, and (2) in opposition to the Board's regulatory proposal.

Attachment

ATTACHMENT A

INTRAVENOUS THERAPY REGULATIONS
SUMMARY AND BOARD RESPONSES TO COMMENTS
JUNE 5 THROUGH JUNE 20, 2002

Attachment A of the *Supplement to Final Statement of Reasons* includes:

- Summaries of representative comments submitted following the publication of OAL's *Decision of Disapproval* and during the 15-day public comment period, June 5 through June 20, 2002, in aggregate categories in (1) Support, and (2) Opposition to the Board's regulatory proposal;

- The Board responses to comments; and

- A numeric list of the public comments submitted and included in the rulemaking file (Attachment A1, *Letters Received Following OAL's Decision*; Attachment A2, *Letters of Support*; and Attachment A3, *Letters of Opposition*).

As noted in the Availability of Second Modified Text, the Board is not required to respond to comments received on aspects of the proposed regulations other than the most recent modifications.

SUMMARY OF COMMENTS AND BOARD RESPONSES

1. SUPPORT COMMENTS

Following are comments representative of support of the Board's proposal, and the Board's response:

- **COMMENTS REPRESENTATIVE OF GENERAL SUPPORT**

  - I strongly support revisions to Article 8. I believe that the recommended revisions clearly identify the services that an appropriately trained LVN is capable of performing in the hemodialysis and pheresis setting and will enable us to better utilize LVNs in our program.

  - The adoption of these regulations is a win-win situation for our dialysis patients and the dialysis community.

  - I hope you will consider the benefits of allowing LVNs to handle the responsibilities that they have done so willingly and so well for the past many years.

- I support BVNPT's modifications to the regulatory language in Article 8, IV Therapy, Section 2542 et seq. I support the revisions as helpful clarifications.

- In reviewing the second modification of the text of the sections in Title 16, California Code of Regulations, I believe the changes would meet the needs of hemodialysis units.

- **COMMENTS REGARDING EVOLUTION IN NURSING PRACTICE**

  - The field of nephrology is seeing more advanced medications introduced into the market, which benefits our dialysis patients. However, the medications are a limited number that are specific to dialysis patients only.

  - During the past thirty years many companies have developed more medications to give the patient a much better quality of life. Giving all the ordered medications properly is a monumental task that leaves little time for the RN to do adequate documentation and patient education, which is the best way to give the patient the very best care, increase their quality and length of life, and reduce hospitalizations.

  - In the early 1970s, most medical professional would have probably thought of "IV fluids" as not including medications, especially in an acute hospital setting. In the dialysis setting, however, even in those years it was clearly a standard of practice for Heparin to be used as part of the dialysis procedure and included in the IV fluids administered by LVNs, hemodialysis technicians, and RNs.

  - As medical practice in dialysis clinics has evolved over the years, we have moved from just Heparin to many other medications that are an integral part of the dialysis procedure and administered as part of the IV fluids through the dialysis circuit.

  - Nursing practice in the dialysis setting has evolved over the past 30 years to include types of medications, techniques, and modes of treatment that were not even conceived in the 1970s.

  - It is clear that the evolution of nursing practice should follow the evolution of technology.

  - Fourteen years ago, we started using LVNs as a means to give our RNs more time to work with the patients. The though was to free them up from routine tasks that don't require their education and expertise to perform.

  - Dialysis is a procedure-oriented treatment. The tasks we perform are repetitive and continuous. This is why over 30 years ago we began to train Patient Care Techs to do dialysis.

  - Having been in the dialysis network for over 20 years, and indeed starting as an LVN, I feel the regulatory changes are appropriate and will not only enhance the role of the LVN in very specific industries of healthcare, but will allow the supervising registered nurses the relief of routine medications given by trained LVNs during the dialysis treatment.

- **COMMENTS REGARDING <u>QUALITY OF CARE AND PATIENT SAFETY</u>**

  - [OAL's decision] will make it even more difficult to provide quality care in my dialysis centers…the decision will increase the likelihood of error and lack of nursing availability.

  - [OAL's decision] ignores the fact that while barring LVNs from performing certain tasks…less educated individuals such as techs are able to do precisely that because their practice is not regulated in the same way as LVNs.

  - The proposed regulations would allow LVNs to conduct needed patient care within dialysis clinic settings. The activities of these individuals will be supervised and competency levels tested and monitored.

  - The medication administration is essential for the proposed regulations. The LVNs should be trained, tested and supervised with medications administration. There are only about ten medications that are used on an ongoing basis in dialysis.

  - LVNs in the dialysis setting have helped to hold down the cost of dialysis without sacrificing any quality of care.

  - As we now use certified technicians who have little or no medical background…it seems appropriate to spend the time required to maintain our high quality LVNs.

  - In limiting LVNs in dialysis, rather than enhancing the nursing role, you may end up compromising patient care.

  - Patients will be benefited by having LVNs given the authority to administer limited medications in a dialysis setting where they have been properly educated and trained.

  - By allowing LVNs the ability to perform these *technical, manual skills*, it would create a greater opportunity for the RN to observe, troubleshoot, and implement a plan of care. The end result would be better patient care.

  - In the specialized environment of the hemodialysis unit, readily experienced and available help is present immediately [to identify and detect potential problems with medication administration].

  - An LVN in our unit was averaging 6 catheter patients a day, 18 per week or 900 treatments a year, times 14 years comes to a total of 12,600 treatments per LVN, <u>without a single adverse outcome.</u>

  - Greater concern is an increased use of unlicensed assistive personnel performing these tasks.

  - There is a RN in charge of the dialysis unit every day.

  - Have worked with LVNs in dialysis setting and found them to be effective in the roles of administering IV medications and accessing central lines.

- This patient group consists of patients that, though they have multiple co-morbid factors, usually receive very routine medication courses in the dialysis facility. The large majority of these medications are associated with very low risk factors for administration, and dose adjustments would remain the RN and /or physician responsibility per protocols.

- The facilities always have at least one RN on the floor, and patients are directly observed in a large, open area as opposed to individual rooms (as you would see in a hospital situation) making direct oversight and availability of the RN more easily achieved than in traditional healthcare settings.

- LVNs have a license with an enforcement mechanism that holds them accountable for their actions in their scope of practice, not to mention being educated in critical thinking which creates a knowledge base for possible outcomes from medications used in this task.

- **COMMENTS REGARDING <u>STAFFING</u>**

  - By limiting the number of nurses available to care for dialysis patients in our units, the OAL is exacerbating a crisis of nursing staffing in this state.

  - The time it takes to administer IV medications is time that could be utilized for higher level tasks that only an RN can do such as assessing patients and patient data to improve patient outcomes.

  - Now is the time to put strategies into action so we can continue to provide quality care to our patients.

  - There are just not enough RNs or all the needs in healthcare.

  - We are not using our qualified, educated, experienced, and licensed staff efficiently. Not allowing LVNs to assume the responsibilities of handling catheters and administering medications seems senseless and irresponsible in light of rising health care costs and the most severe shortage of RNs in my lifetime.

  - To get through this [nursing] crisis we need to find a means to utilize our RNs in ways that maximize the use of their unique knowledge, skills and experience for the benefit of patients.

  - LVNs are needed in light of the ever-increasing role of the RN in California and the RN shortage.

  - With the shortage of RNs, and because I believe LVNs are trained adequately to administer these drugs in this setting, these changes will assist us in providing quality care to our patients.

  - In this time of documented nursing shortage - every available RN and LVN is critical to the well-being of our nation's health care. There are thousands of patients on hemodialysis across the nation. Currently we have no known incidents related to

LVNs accessing grafts, fistulas and central lines or to administering IV heparin in our facilities. We would like to strongly encourage the continual use of LVNs in this capacity. To limit their ability to care for these patients would further reduce the available nurses needed for this ever-growing population.

- Actual administration of the routine medications, due to the volume of the patients and medications, often becomes a time-consuming task that keeps the registered nurse from more important functions of the RN duties. Having the trained and licensed personnel attending the routine part will free RN for observation, where his/her skills are needed.

- **OTHER COMMENTS**

  - In the real world, LVNs are a very valuable and integral part of dialysis in their knowledge and ability to function as they do.

  - It is a waste of license not to allow LVNs to perform these procedures.

  - Please do not take away the career that we love.

  - LVNs are an asset to the team and are effective in administration of IV medications, accessing central lines for dialysis, basic nursing assessment of patients, and taking and transcribing of physician orders.

  - [LVNs are] nurses who have a well-grounded background in anatomy and physiology, posses good clinical skills, and a sound understanding of their role in our unit.

BOARD RESPONSE:

The Board accepts these comments as further substantiation of the safety, appropriateness, and validity of the proposed regulatory action.

2. OPPOSITION COMMENTS

Following are comments representative of opposition to the Board's proposal, and the Board's response:

- **COMMENTS RELATED TO STANDARD OF REVIEW**

  - The submitted documents fail to meet the Office of Administrative Law's standard for further review and consideration as outlined in its April 19, 2002, Decision of Disapproval. Specifically, the record does not contain facts, studies, expert opinion or other information which shows that professional in the field would consider medications an integral component of intravenous fluids.

BOARD RESPONSE:

The Board has met the requirements set forth in OAL's April 19, 2002, Decision of Disapproval justifying OAL's approval of the regulations. As disclosed in its Notice of Additional Material Relied Upon, the Board has provided facts, studies and expert opinion or other information which shows that professionals in the field would consider medications and integral component of intravenous fluids. The Board respects the opponent's rights to differ in their opinion, however, as long as the Board's opinion is reasonable, as it is here, the regulation may be lawfully adopted.

- **COMMENTS RELATED TO STATUTORY AUTHORITY**

  - The Board exceeded its statutory authority.

  - The conclusion by legal counsel that that Board has statutory authority to amend its regulations to permit LVNs to administer intravenous fluids including medications is predicated on the supposition that the term "intravenous fluids" includes intravenous medications. Such a supposition is not consistent with legislative intent.

  - The Board has no legal authority to expand the scope of practice. This should be done by the Legislature.

  - The newly proposed language will require the LVN to make judgments and engage in nursing activities outside the scope of their practice act.

  - The authority to implement, interpret, or make specific does not include the authority to expand the scope of practice of LVNs.

  - The proposed regulations to allow LVNs to administer IV medications goes beyond the scope of practice authorized by statute, and cannot be considered an implementation of it. The absence of statutory authority is the primary problem with the regulatory proposal.

  - The existing statute authorizes LVNs to start and superimpose IV fluids; it does not authorize LVNs to administer IV medications as proposed in Category II.

  - The proposed regulations would have the effect of greatly expanding the original intention of the statute, which we believe is for the LVN to have a very limited role in providing IV therapy.

  - The lack of statutory authority is further evidenced by 13 Health Manpower Pilot Projects (HMPP) approved by the Office of Statewide Health Planning and Development (OSHPD) between 1983 and 1994.

  - The June 5, 1974, final amended version of 1973-74 AB 3618 (Alatorre) specifically deleted language that would have given the authority for LVNs to administer medications as part of intravenous therapy.

- Legal counsel ignores the fact that "intravenous fluids" have been defined in the B&P Code since 1975 as fluid solutions of electrolytes, nutrients, vitamins, blood and blood products. In 1993, the BVNPT issued an interpretation in an opinion letter to Michael Smith, RN that LVNs cannot administer medications intravenously.

- The June 4, 2002, opinion of staff counsel fails to demonstrate that legislative history and intent was not the exclusion of the administration of intravenous medication from the LVN scope of practice.

BOARD RESPONSE:

The Board rejects these comments. The Board is authorized to adopt these regulations pursuant to the authority vested by section 2854 of the B&P Code to implement, interpret or make specific section 2860.5.

Most, if not all, of these comments are addressed in the June 4, 2002, opinion of the Board's legal counsel. Without repeating the entire opinion here, the Board finds that legal opinion and analysis more persuasive as to the authority issue than the opponents comments.

Several of the comments contain logical flaws. In particular, they imply that because fluids are defined in the current regulation to include only electrolytes, nutrients, blood and blood products, that the definition of fluids can never change. Simply because that was the definition does not mean that it cannot change. Similarly, the positions taken by a previous Board in years past are not controlling of the ability of the Board to change its position. Further, the regulation change does not require a vocational nurse to do anything; it simply formalizes a task into vocational nurses' scope of practice which they have been doing for some time now without event.

The plain meaning of the statute should control how the statute should be read. The term "fluids" generally refers a substance that is liquid in form. Such a definition is consistent with the proposed regulations. Simplified, the words of the statute clearly permit the proposed regulatory definition of intravenous fluids.

Comments suggest that the provision that was deleted from AB 3618 before it was passed (creating the existing text of section 2860.5), and its absence in the enacted version of the statute, indicate the lack of authority. To the contrary, although language is often deleted in bills in order to appease opponents, it is often with the knowledge that the language of the remaining bill can still be read to authorize the activity creating the controversy.

Comments also suggest that, unlike the Nursing Practice Act, the Vocational Nursing Practice Act does not allow any flexibility in the vocational nurse's scope of practice. To the contrary, a certain amount of flexibility is inherent in the Vocational Nursing Practice Act because, by its nature, the technical, manual tasks provided by vocational nurses change. Although they do not have the extremely broad language that is written into the Nursing Practice Act and the same amount of flexibility that language offers, it cannot be denied that the roles and skills of all nursing practitioners change. This is particularly so in light of the explicit authorization of standardized procedures with respect to IV therapy in B&P Code section 2860.5; the authority for standardized procedures, unique to the

practice of IV therapy, gives more flexibility to in the interpretation of IV therapy than any other services provided by an LVN. Arguments to the contrary appear to be based in protecting the scope of practice of registered nurses and preventing other practitioners from taking away demand for registered nursing services.

Indeed, in vetoing 1973's AB 965 (which was a bill that proposed similar changes regarding intravenous therapy as well as dealing with registered nursing practice), then Governor Ronald Reagan noted in his veto message that there was a "need to redefine what is regulated by licensing laws – to provide for change, and especially to permit registered nurses and licensed vocational nurses to expand the usefulness of their services within the team of health workers." He went on to explain that he was concerned that if the bill became law, the language might be interpreted to restrict and narrow the scope of practice for nurses, and that a "partial listing of specific items would be interpreted by the courts to exclude from nursing practice a much larger (and changing) group of procedures that are not included in the bill." As evidenced by these statements, the practice of nursing is not fixed, but flexible, not just for registered nurses, but also for licensed vocational nurses.

The clarifications within the proposed regulations do not expand the original intention of the statute, in which the LVN has a limited role in providing IV therapy. The role of the LVN in the administration of IV fluids continues to be limited to the use of technical, manual skills to administer a course that has been prescribed by a physician. An LVN still cannot independently determine that a particular therapy is warranted. To ensure consumer safety, the Board is further clarifying those circumstances by these regulations.

Comments suggesting that a lack of statutory authority is evidenced by Health Manpower Pilot Projects approved by the Office of Statewide Health Planning and Development between 1983 and 1994, were addressed in the original submission.

In summary, those comments that suggest that the Board has no authority are in error. As explained here and in the Board counsel's June 4, 2002, opinion, the Board's interpretation is an entirely reasonable one. The Board is charged with enforcing the laws pertaining to licensed vocational nurses and ensuring their practice is safe to consumers. This interpretation is one delegated to the Board's judgment to make.

- **COMMENTS REGARDING <u>CLARITY</u>**

  - [There is] concern regarding the lack of a minimum training standard being clearly outlined in the proposed regulations.

  - [There is] concern regarding the lack of definition of the term "immediate vicinity" in the proposed regulations.

  - There are 368 Dialysis Centers in the state of California. Allowing each these health care systems to develop 'standard procedures' does not insure a standard of care throughout the state.

BOARD RESPONSE:

The Board rejects these comments. With the most recent modification clarifying the term "immediate vicinity," the proposed regulations clearly communicate the intent of the Board to those persons directly affected. It would not be possible to define the term "immediate vicinity" in regulation so that the definition would be universally appropriate for all hemodialysis, pheresis or blood bank settings. The modification to the text of the proposed regulations adds requisite clarity by explaining that the term "immediate vicinity" is defined by the organized health care system in its standardized procedure. By specifying that the term "immediate vicinity" be defined by each facility in accordance with its staffing structure and with respect to the unique layout of its physical plant ensures consumer protection.

With respect to minimum training standards, the Board agrees that additional training is necessary in order for the LVNs to take on this role; however, attempting to define a specific training program in regulation that would be appropriate for all hemodialysis, pheresis or blood bank settings does not ensure consumer protection. The modification to the text of the proposal adds requisite clarity by explaining that the organized health care system would assure that the LVN receives the needed specialized training and, most importantly, assesses the LVN's competence in performing the required procedures.

- **COMMENTS REGARDING <u>EVOLUTION OF NURSING PRACTICE</u>**

  - The Vocational Nursing Practice Act contains no language that recognizes that the practice of vocational nursing is a dynamic field, the practice of which is continually evolving to include more sophisticated patient care activities. Therefore, any reference in the legal opinion regarding the evolution in the practice of vocational nursing must be rejected.

  - A distinction has always been made between intravenous fluids and intravenous medications. The notion that medications are a necessary component of intravenous fluids (integral to) is inconsistent with any known standard of medical or nursing practice.

  - The June 4, 2002, opinion of staff counsel fails to show that Category II medications are an integral component of intravenous fluids.

  - "Fluids," as the term is commonly used, does not include medication. The administration of intravenous medication is a procedure distinct from the administration of intravenous fluids.

  - [There is] concern that the legal opinion states that intravenous administration of a larger class of medications has become common and accepted and therefore the practice has evolved. The Board has in fact aided and abetted LVNs in the violation of the provision of their practice act. The Board is in violation of its mandate to protect the public welfare and is not enforcing its standards of practice.

BOARD RESPONSE:

In its *Decision of Disapproval*, OAL specifically stated that if the Board can supplement the record with facts, studies, expert opinion or other information that tends to show this **evolution in nursing practice**, these regulations could be resubmitted. This issue is also discussed in conjunction with the Board's response to comments regarding authority.

The materials submitted by the Board clearly demonstrate such an evolution in nursing practice. Those materials include:

- Testimony from medical experts in the field of dialysis;
- Survey results concerning LVN scope of practice throughout the United States; and
- Statements from professional organizations associated with IV therapy, which identify the role of LVN in administration of IV medication.

As technology and associated nursing practice has advanced, administering IV fluids has become a technical, manual skill that an LVN can perform safely under controlled conditions. Clarifying the definition of IV fluids to reflect its contemporary definition is a reflection of the evolution of technology and nursing practice.

The argument that IV medications are not understood to be the same as IV fluids may not be clear-cut; but the notion that medications are a necessary component of intravenous fluids is not inconsistent with known standards. For example, Missouri, in its nursing regulations, refers to "Intravenous Fluid Treatment Administration" and includes medications as part of the IV fluid treatment. Pennsylvania regulations state that "The LPN may perform venipuncture and administer and withdraw intravenous fluids…"; those fluids identified may include medications. In the California law for hemodialysis technicians (see B&P Code section 1247.3), heparin and sodium chloride are both referred to as medications that, in the form of solutions (fluids), may be administered by a hemodialysis technician. According to the plain meanings of the terms "intravenous," "solution," and "fluids," medications in a fluid (or solution) form which can be administered intravenously are clearly intravenous fluids.

Opponents submitted copies of preprinted physician order forms from a large healthcare organization as evidence that IV fluids and medications are different. Medical forms from a specific health care organization are an example of the use of those terms in that organization, but not evidence of the appropriate application of any medical terms. Most importantly, it is the Board which is charged with administering, interpreting, and implementing the term "intravenous fluids" as used in B&P Code section 2860.5.

- **COMMENTS REGARDING THE ADDITIONAL MATERIAL RELIED UPON**

Material: **Positions of Professional Organizations Associated with IV Therapy**

- The referenced professional organizations support the use of LVNs with the caveat that the practice must be within the scope of practice stated in the regulations of the particular state. It is not within the scope of practice for LVNs in California to administer IV medications.

BOARD RESPONSE:

The Board is promulgating these regulations in order to clarify that the practice of administration of IV medications in hemodialysis, pheresis and blood band settings is within the LVN scope of practice.

- According to the Intravenous Nurses Society (INS) standards presented, "To meet the requirements to enter the specialty [of IV nursing], the LPN/LVN must have one-year experience (i.e., 1600 hours in the care and delivery of IV therapy to patients within the last two consecutive years) and have national certification." LVNs have neither.

BOARD RESPONSE:

The opponents misquoted the INS standards. In fact, on page S9 of the "Revised IV Nursing Standards of Practice," the stated requirements "For entering the specialty" include a LPN/LVN license; two years experience in a medical-surgical environment and no national credential. If the LPN/LVN wishes to move on and become designated as an "IV Nurse" by the INS she must acquire one year's experience in IV therapy (defined as 1600 hours in the care and delivery of IV therapies to patients within the last two consecutive years). It is also "recommended," though not required, that the LPN/LVN complete the national Licensed Practical/Vocational Nurse IV Certification (CLNI).

The import of the INS standards is that the standards recognize that with additional training the LVN can play an important role in IV therapy. IV certified LVNs in California have already completed education in addition to their basic vocational nursing curriculum. The proposed regulations stipulate that in order for LVNs to administer medications in hemodialysis, pheresis or blood bank settings the LVN must receive additional specialized instruction in the proper procedure from a registered nurse or licensed physician and demonstrate to a registered nurse or licensed physician the requisite knowledge, skills and abilities to perform the procedure. The required method of the specialized instruction and demonstration of competence is to be documented in a standardized procedure developed by the hemodialysis, pheresis or blood bank setting.

- The Position Statement from Renal Network is from Network 9 and 10 not Networks 17 and 18 which are in California so should not apply.

BOARD RESPONSE:

The position statement from Renal Network is used as example of evolution of practice. Professionals within the dialysis community are recognizing the importance of LVNs/LPNs as part of the dialysis care team. End Stage Renal Disease Networks 17 and 18 in California have not published a position statement regarding LVNs in the dialysis setting.

Material: **Expert Opinion**

- The letters of support do not address the questions raised by OAL.

- The opinions of physicians must be rejected because they have a vested interest in allowing the practice to continue and are not backed up by scientific data. Opinions which rely upon relevant data collected, compiled, and maintained by government agencies have a greater reliability and credibility.

- The letters submitted by "experts" have internal inconsistencies that conflict with the published experts' opinion contained in the Dialysis Therapy Guide.

- BVNPT legal counsel is not an expert who can or should define medical or nursing practice.

BOARD RESPONSE:

The Board received opinion from medical professionals who are recognized leaders in dialysis settings in California who have had many years of experience in the field of hemodialysis. During the initial public comment periods for these regulations, strong letters of support were submitted by nephrologists who are recognized leaders in the field. One such letter was submitted by Dr. Allen Nissenson, acknowledged as an expert by opponents of these regulations. On October 10, 2001, Dr. Nissenson wrote:

> "I am a Professor of Medicine and have been Director of the Dialysis Program at UCLA since 1977. I am strongly in support of the proposed regulations to permit LVNs to administer certain medications during dialysis treatments. The dialysis community is suffering from a tremendous shortage of registered nurses, and is relying to a much greater extent than in the past on LVNs to participate in the dialysis procedure. At the same time, medical advances have led to the availability of a variety of intravenous medications that are of great clinical benefit to patients, and are given to the vast majority of patients during dialysis.
>
> The end result of these two factors is tremendous pressure on RNs to spend the majority of their time injecting medications rather than truly caring for the patients. This is not good for patients and greatly damages the morale of the nurses.
>
> Permitting LVNs to administer these medications will be of benefit to patients, professionals, and in the best interest of the public."

Dr. Thomas Paukert, President of the California Dialysis Council, specifically addresses the issue of "evolution in the field of nursing practice. In his letter of May 30, 2002, Dr. Paukert states:

> "In the early 1970's, most medical professionals would have probably thought of 'intravenous fluids' as not including medications, especially in an acute hospital setting. In the dialysis setting, however, even in those years it was clearly a standard of practice for Heparin to be used as part of the dialysis procedure and included in the intravenous fluids administered by LVNs,

hemodialysis technicians and RNs. As medical practice in dialysis clinics has evolved over the years, we have moved from just Heparin to many other medications that are an integral part of the dialysis procedure and administered as a part of the IV fluids through the dialysis circuit. The beneficial impact of these medications has been considerable. Examples are Epogen, TPA and various Vitamin D analogues that are administered every dialysis session to certain patients.

In short, nursing practice in the dialysis setting has evolved over the past 30 years to include types of medications, techniques, and modes of treatment not even conceived in the 1970s. It is clear that the evolution of nursing practice should follow the evolution of technology. In a dialysis setting, the patient receives IV fluids and medications as an integral part of dialysis care in the closely monitored setting. These medications are safe, have virtually no potential for acute allergic or idiosyncratic reaction and are given on a regular, repetitive basis. They should be included in the set of IV fluids that an LVN can administer in the chronic dialysis setting."

The opinions of these experts need not be dismissed because they may have a financial interest in the result of a rulemaking proceeding. Indeed, if that was the standard for accepting comments, few comments would ever be accepted – including in this proceeding. The Board reviewed all the evidence and found their opinions credible.

Legal counsel's opinion is offered to address the authority issues, and she is not offered as a medical expert.

Material: **Survey of Practice in Other States**

- It doesn't matter what LVNs can do in other states.

- With regard to the survey of other states, the laws in other states do not apply in California.

BOARD RESPONSE:

The survey of LVN scope of practice in other states addresses evolution of nursing practice relative to expanded administration of IV fluids, including medications. Forty-four states responded to the Board's survey. Although each state may approach regulation of the activity differently, all 44 states permit LVNs/LPNs to administer expanded medicated IV fluids. Regulations in the most restrictive state limit administration of medicated IV fluids to antibiotics via peripheral lines; regulations in the least restrictive state allow LVNs/LPNs to administer a wide variety of medicated fluids through both peripheral and central lines. When questioned, some states indicated that they do not provide "laundry lists" of tasks, but rather base scope of practice on the individual nurse's training and competence. Louisiana's statement is one such example:

"Scope of practice is a fluid concept. It changes as knowledge and technologies expand. LPNs must possess the knowledge, skill and ability to perform their duties, therefore, scope of practice comes down to the competency of the individual LPN."

In the final analysis, the results of the survey indicate that the LVN/LPN role in the United States has evolved to include administration of an expanded range of IV fluids.

- **COMMENTS RELATED TO <u>QUALITY OF CARE AND PATIENT SAFETY</u>**

[Although the Board is not required to respond to this issue in this resubmission of the regulation, it wishes to do so because of its mandate of consumer protection.]

- When medications are administered intravenously, there is the potential for life-threatening emergencies, including an anaphylactic reaction, to occur.

- Concern about the lack of a minimum training standard with respect to the regulations. Without minimum standards, there is no way to ensure a consistent level of knowledge by LVNs administering medications in these types of settings.

- [There is] concern that there is no definition set or minimum standard set for the term "immediate vicinity."

- Allowing each health care system to develop standard procedures does not ensure a standard of care throughout the state.

- There is no mandatory reporting of sentinel or adverse events in the ESRD program. In fact, we have no data, from any source, on what practices are safe in this arena of care.

- The proposed second modified text, wherein the definition of "immediate vicinity" is set forth in the standardized procedures of each facility, fails to clearly define the distance between the LVN performing the proposed procedures and the supervising physician or registered nurse.

- [There is] concern about the lack of scientific outcome studies in this area (hemodialysis) of medicine and nursing. There is no evidence of self-regulation in the industry.

<u>Board Response:</u>

There is no question that IV fluids enter the patient's system rapidly and patients can react quickly. However, there is no less potential for adverse reaction to the IV fluids the LVN is currently authorized to administer such as blood and potassium. As an adverse reaction can be deadly if not treated appropriately, LVNs are taught how to recognize and respond to symptoms of adverse reactions and are taught to immediately notify a registered nurse or licensed physician.

The Department of Health Services (DHS) expressed concern over the issue of patient safety in a January 10, 2002, meeting with the Board on the proposed regulations; however, DHS provided no evidence that medication errors or poor patient outcomes increased when LVNs began administering IV medications in dialysis settings.

It is unrealistic to presume that, given his/her other responsibilities, the RN is always able to stay at the patient's bedside to observe for adverse effects after administering medicated IV fluids. This task is most often performed by an LVN or a hemodialysis technician. In so doing, the LVN enables the RN to do those things that only an RN can do. It is clear that efficiency would be improved without compromise to patient safety if the LVN would administer more medicated fluids, observe for effects, and bring the RN/physician to the bedside when needed.

Consumer protection is ensured when an LVN performs the task of observing a patient after medicated fluid administration. LVNs receive specialized instruction within the health care organization and are required to demonstrate competence in administering IV therapy before being allowed to function in this capacity; the education and experience requirements for hemodialysis technicians, who are not subject to the rigors and accountability of licensure, are less than half that required of the LVN.

- LVNs lack the assessment skills to care for patients receiving IV medications.

- LVNs do not have the knowledge base or theoretical background to understand the use of IV medication and its total effects on patients and their health.

BOARD RESPONSE:

Skills for the assessment of physical and mental status are taught in the vocational nursing curriculum. In addition, the pharmacology course required in all vocational nursing programs, teaches students the importance of knowing the actions, side effects and adverse effects of medications that they are administering. Students are also taught to recognize adverse effects and report them immediately to an RN or physician.

- If the regulatory change were to go into effect patient care would be harmed.

- There is a lack of "existing scientific outcome studies" related to this issue.

BOARD RESPONSE:

The Board sought hard data related to administration of medicated IV fluids by LVNs. When asked, DHS was unable to provide such data. The only data available came out of the HMPPs facilitated by the OSHPD. Those projects, although not within the jurisdiction of the Board, allowed LVNs to administer medicated IV fluids. Although the projects were never completed due to administrative difficulties, the resulting data is pertinent. The projects took place in acute care hospitals between 1994 and 1997. During that timeframe LVNs administered 3370 doses of IV antibiotics to 1830 patients. The final reports on these projects indicate that "there were no adverse reactions or medication errors attributed to LVN administration of medication." This data

demonstrates that LVNs are capable of administering medicated IV fluids without causing patient harm.

One opponent quoted text from the book, Dialysis Therapy, edited by Allen R. Nissenson, M.D. and Richard N. Fine, M.D. to support her opposition to these regulations based on concern for patient safety. The book discusses dialysis therapy, but does not discuss nursing roles related to that therapy. As quoted earlier in this document, the rulemaking file contains a letter of support from Dr. Allen Nissenson, Director of the UCLA Dialysis Program, one of editors of this book and an expert in the field that does not share the opponent's concerns.

Finally, another opponent attempted to use a May 2002 article from the New England Journal of Medicine, Nurse Staffing Levels and the Quality of Care in Hospitals, to prove that LVNs should not be administering medications in dialysis settings. This argument demonstrates flawed use of information. The article did not address LVNs administering IV medications, so does not speak to the issue at hand. Secondly, the opponent's interpretation of the results of the study is flawed. The study's author states, "A higher proportion of hours of nursing care provided by registered nurses and a greater number of hours of care by registered nurses per day are associated with better care for hospitalized patients." The article goes on to state, however, that the authors, "found no association…between increased staffing by licensed practical nurses or nurse's aides and the rate of adverse outcomes." The authors also state "…the level of staffing by nurses is an incomplete measure of the quality of nursing care in hospitals. Other factors, such as effective communication between nurses and physicians and a positive work environment have been found to influence patient outcomes." The article does not support the opponent's arguments.

	Hemodialysis Regulations: LETTERS IN SUPPORT OF RESUBMISSION -		**A1**
	Comments Received Prior to June 5-20, 2002, Public Comment Period		
	Name or Organization	**Number of Signatures**	
1	Napa Valley Nephrology & Internal Med., California Dialysis Council, MD, President	**1**	
2	Balboa Nephrology Medical Group, Inc., MD	**1**	
3	Gambro Healthcare, MD, Medical Director	**1**	
4	Gambro Healthcare, RN, BSN, MBA, Regional Director	**1**	
5	Satellite Dialysis, BSN, CNN	**1**	
6	Fresenius Medical Care, Inc., RN, CNN, Regional Manager	**1**	
7	Burbank Dialysis Parternership, RN, BS, Administrator	**1**	
8	California Pacific Medical Center, RN, CNN	**1**	
9	Gambro Healthcare Los Gatos, RN, Center Director	**1**	
10	RN, BSN, PHN	**1**	
11	Gambro Healthcare, RN, CNN, Center Director	**1**	
12	Kaweah Delta Healthcare District, RN, Staff Nurse	**1**	
13	Fresenius Medical Care, Inc., RN, CNN, Clinic Manager	**1**	
14	Fresenius Medical Care, MS, RD	**1 form ltr**	
15	Fresenius Medical Care, RN, Charge Nurse	**1 form ltr**	
16	Fresenius Medical Care, RN	**1 form ltr**	
17	Fresenius Medical Care, RN, Clinic Manager	**1 form ltr**	
18	Fresenius Medical Care, RN, CNN	**1 form ltr**	
19	Fresenius Medical Care, RN	**1 form ltr**	
	Total Letters of Support = 19 **Total Signatures = 19**		

	Hemodialysis Regulations: LETTERS OF SUPPORT - June 5 through June 20, 2002		
	Name	**Signatures**	**Affiliation**
1	CEO Kent J. Thiry	**1**	Davita
2	Pres./CEO Larry C.Buckelew	**1**	Gambro
3	RN BSN CNN MBA A.M. Ford	**1**	None noted
4	RN CNN Sandra Wilson	**1**	Kidney Center, Inc.
5	RN Kathy Gage Ivers	**1**	None noted
6	LVN Beatrice M. Bell	**1**	None noted
7	RN MSN CNN E. Whitacre	**1**	Davita
8	RN CNN M.G. Marmolejo	**1**	Bakersfield Dialysis Center
9	RN M. Gammod	**1**	Mission Dialysis
10	RN Nerita Quinto	**1**	Mission Dialysis
11	RN Aida Smith	**1**	Mission Dialysis
12	RN CNN Susan Vogel	**1**	S. Valley Regional Dialysis Center
13	LVN Robert G. VaVuris	**1**	None noted
14	LVN Kathy Mears et al	**4**	None noted
15	RN Linda Wagoner	**1**	Davita Acute Dialysis
16	RN Mary Ann Humphrey	**1 (16-184 = form ltr.)**	Beverly Hills Dialysis Los Angeles
17	RN Lynda Hicks	**1**	Davita
18	RN Cynthia Smith Holbert	**1**	Mission Dialysis San Diego
19	RN Alexander Cruz	**1**	Davita Sunrise Hawthorne
20	RN Antonio Cabillan	**1**	Davita Sunrise Hawthorne
21	RN Corazon Aranda	**1**	Davita Sunrise Hawthorne
22	RN Carola Becker	**1**	Davita Sunrise Hawthorne
23	RN Joan Alexander	**1**	Davita Sunrise Hawthorne
24	RN Margarita Dano	**1**	Davita Antelope in Antelope
25	RN Jane Woo	**1**	Pacific Coast Inglewood
26	RN Rosemary Anderson	**1**	Davita-DBC Acutes in Hayward
27	RN Peggy Miller	**1**	Chico Dialysis Center - Chico
28	RN Linda Paillon	**1**	Chico Dialysis Center - Chico
29	RN Janice West	**1**	Chico Dialysis Center - Chico
30	RN Cindy Barnard	**1**	Davita Dialysis San Leandro
31	RN Mary E. White	**1**	Davita/DBC Acutes in Hayward
32	RN Marina Ryabina	**1**	CHDC Los Angeles
33	RN Regina Krivitskaya	**1**	CHDC Los Angeles
34	RN Galina Kolesnik	**1**	CHDC Los Angeles
35	RN Chung Jung Soon	**1**	Davita Crescent Heights Los Angeles
36	RN Rosa Arevalo	**1**	Davita Crescent Heights Los Angeles
37	RN Alexander Khutorseoy	**1**	Davita Crescent Heights Los Angeles
38	RN Manuela Cayabyab	**1**	Mission Dialysis San Diego
39	RN Rosemarie Quicho	**1**	Mission Dialysis San Diego
40	RN Maritess Pingol	**1**	Mission Dialysis San Diego
41	RN Victoria Fedalizo	**1**	Mission Dialysis San Diego
42	RN Eloida Limiueco	**1**	Mission Dialysis San Diego
43	RN Jovita Sicat	**1**	Mission Dialysis San Diego
44	RN Aleta Vallarta	**1**	Mission Dialysis San Diego
45	RN Lito Sadangsal	**1**	Mission Dialysis San Diego
46	RN Susan Gilliland	**1**	Davita Hemet San Jacinto
47	RN Borjum last undeciferable	**1**	University Park Los Angeles
48	RN Rene Magsino	**1**	University Park Los Angeles
49	RN Rita Onwgnna	**1**	University Park Los Angeles
50	RN Cang Nguyen	**1**	University Park Los Angeles

	Hemodialysis Regulations: LETTERS OF SUPPORT - June 5 through June 20, 2002		
	Name	**Signatures**	**Affiliation**
51	RN Emeliana Robles	**1**	University Park Los Angeles
52	RN Jonathan Yanga	**1**	University Park Los Angeles
53	RN Lizette Sajo	**1**	University Park Los Angeles
54	RN Sunita Masili	**1**	Davita Hemet San Jacinto
55	RN Nancy Smith	**1**	Salinas Dialysis Salinas
56	RN Fleurdeliz Balmaceda	**1**	Davita Fairfield Dialysis Fairfield
57	RN Marites Cordero	**1**	Davita Fairfield Dialysis Fairfield
58	RN Tyra LaChapelle	**1**	Davita Fairfield Dialysis Fairfield
59	RN Rosalee Cordero-Medina	**1**	Davita Fairfield Dialysis Fairfield
60	RN May S. Arias	**1**	Kenneth Hahn Plaza Dialysis Center LA
61	RN Virginia Brady	**1**	Kenneth Hahn Plaza Dialysis Center LA
62	LVN Dolores Granados	**1**	Gambro Healthcare Tulare
63	Admin. Dir. Judith Filangeri	**1**	UCSD Dialysis Program
64	RN Heather Beavert	**1**	Lodi Dialysis Lodi
65	RN Cheryl A. Bergo	**1**	Napa Dialysis Center Napa
66	RN P Gaines	**1**	Napa Dialysis Center Napa
67	RN Signature undeciferable	**1**	Napa Dialysis Center Napa
68	RN Chris Moore	**1**	Lodi Dialysis Lodi
69	RN Ilene M. Cress	**1**	Napa Dialysis Center Napa
70	RN Leslie Mechling	**1**	Lodi Dialysis Lodi
71	RN Teresa Lopez	**1**	Lodi Dialysis Lodi
72	RN Rowena Dizon	**1**	Napa Dialysis Center Napa
73	RN Josefina Bigornia	**1**	South Sacramento Dialysis Sacramento
74	RN Digna Soliman	**1**	South Sacramento Dialysis Sacramento
75	RN Grace Paraiso	**1**	South Sacramento Dialysis Sacramento
76	RN Carol Maghinay	**1**	South Sacramento Dialysis Sacramento
77	RN Corazon Bellosius	**1**	Davita DBC Acutes-Hayward
78	RN Diana L. Ferguson	**1**	Davita DBC Acutes-Hayward
79	RN Gary Uy	**1**	Davita DBC Acutes-Hayward
80	RN Minda Manzanho	**1**	Beverly Hills Dialysis Los Angeles
81	RN Stella Li	**1**	Beverly Hills Dialysis Los Angeles
82	RN Tenry Commeans	**1**	Davita Hemet San Jacinto
83	RN Erlinda Vinaya	**1**	University Park Los Angeles
84	RN James G. Fowlds	**1**	Eaton Canyon Dialysis Center Pasadena
85	RN Dennis Bantagan	**1**	Beverly Hills Dialysis Los Angeles
86	RN Floenda G. del Rosario	**1**	Beverly Hills Dialysis Los Angeles
87	RN Chow Chen	**1**	Beverly Hills Dialysis Los Angeles
88	RN Mae Billanes	**1**	Beverly Hills Dialysis Los Angeles
89	RN Janice Bernaldez	**1**	Mission Dialysis San Diego
90	RN Alma Janaban	**1**	Mission Dialysis San Diego
91	RN Jo Ann Laing	**1**	Davita University Dialysis Center Sac
92	RN Suzette Quilay	**1**	Davita University Dialysis Center Sac
93	RN J. Sopolsky	**1**	Davita University Dialysis Center Sac
94	RN Glory Fernandez	**1**	Davita University Dialysis Center Sac
95	RN Emilia Tucay	**1**	Davita Dialysis Santa Ana
96	RN Tran Tu-Hong	**1**	Davita Dialysis Santa Ana
97	RN Zohneh Masjudi	**1**	Davita Dialysis Santa Ana
98	RN Pamela Lorenzen	**1**	Davita Dialysis Yuba City
99	RN Signature undeciferable	**1**	Napa Dialysis Center Napa
100	RN Phyllis O'Shaughnessy	**1**	Davita Dialysis Yuba City

	Hemodialysis Regulations: LETTERS OF SUPPORT - June 5 through June 20, 2002		
	Name	**Signatures**	**Affiliation**
101	RN Carmen Chalfant	**1**	Davita Dialysis Yuba City
102	RN Maria Ida N. Eloja	**1**	Davita Dialysis Pleasanton
103	RN Annette M. Munson-Hall	**1**	Hemet Dialysis Hemet
104	RN Emma C.O. Bautista	**1**	Davita Fairfield Dialysis Fairfield
105	RN Sherry Buethe	**1**	Davita Dialysis Yuba City
106	RN Mikhail Shneyder	**1**	Piedmont Dialysis Center Oakland
107	RN Charisma M. Serrano	**1**	Piedmont Dialysis Center Oakland
108	RN Rosa M. Salinas	**1**	Kenneth Hahn Plaza Dialysis Center LA
109	RN Josie Obracevic	**1**	Kenneth Hahn Plaza Dialysis Center LA
110	RN Alfonso Lopez	**1**	Kenneth Hahn Plaza Dialysis Center LA
111	RN Jackie Siruno	**1**	Orangevale Dialysis Center Folsom
112	RN Geri Hargreaves	**1**	Orangevale Dialysis Center Orangevale
113	RN Takaks Harris	**1**	Premier Davita Dialysis Center Cudahy
114	RN Christine Lubos	**1**	Premier Davita Dialysis Center Cudahy
115	RN Belen L. Villajin	**1**	Premier Davita Dialysis Center Cudahy
116	RN Ronnie Batino	**1**	Premier Davita Dialysis Center Cudahy
117	RN Emily G. Sunga	**1**	Premier Davita Dialysis Center Cudahy
118	RN Maria Victoria Lasam	**1**	Premier Davita Dialysis Center Cudahy
119	RN Kitty Wu	**1**	Montclair Dialysis Center Montclair
120	RN Doreen Gorman	**1**	Montclair Dialysis Center Montclair
121	RN Phyllis Shaffer	**1**	Fresenius Medical Care
122	RN Deborah R. Sczepczenski	**1**	Montclair Dialysis Center Montclair
123	RN Faye Torres	**1**	Montclair Dialysis Center Montclair
124	RN Karin H. Saeger	**1**	Davita Dialysis Center Riverside
125	RN Paulette Marline Cole	**1**	Riverside Dialysis Center Riverside
126	RN Juliana Urriquia	**1**	Riverside Dialysis Center Riverside
127	RN Kristin Kehrier	**1**	Doctors Dialysis Montebello
128	RN Signature undeciferable	**1**	Doctors Dialysis Montebello
129	RN Nor Ingram	**1**	Doctors Dialysis Montebello
130	RN Patricia Carlin	**1**	Doctors Dialysis Montebello
131	RN Roberta Ocfemia	**1**	Doctors Dialysis Montebello
132	RN Linda Sherman	**1**	Riverside Dialysis Center Riverside
133	RN Corrine Hall	**1**	Riverside Dialysis Center Riverside
134	RN Rowena Borromeo	**1**	Riverside Dialysis Center Riverside
135	RN Eleanor Pagtakhan	**1**	Mission Dialysis San Diego
136	RN Francina Villasenor	**1**	Mission Dialysis San Diego
137	RN Nick Bassett	**1**	Mission Dialysis San Diego
138	RN Guilan Bao	**1**	Mission Dialysis San Diego
139	RN Anna Kim	**1**	Davita Dialysis San Leandro
140	RN Diane Wells	**1**	Corona Dialysis Corona
141	RN Michael M. Javier	**1**	Piedmont Dialysis Center Oakland
142	RN Signature undeciferable	**1**	Valley Dialysis Van Nuys
143	RN Nancy Kim	**1**	Davita Dialysis San Leandro
144	RN Mollie Biancalana	**1**	Davita Dialysis San Leandro
145	RN Nancy Ann James	**1**	Valley Dialysis Van Nuys
146	RN William Littlejohn	**1**	Valley Dialysis Van Nuys
147	RN Yoo Soo Le	**1**	Valley Dialysis Van Nuys
148	RN Angie Pamilar	**1**	Corona Dialysis Corona
149	RN Martha Borth	**1**	North Highlands Dialysis Center
150	RN Berta Lockwood	**1**	North Highlands Dialysis Center

	Hemodialysis Regulations: LETTERS OF SUPPORT - June 5 through June 20, 2002		
	Name	**Signatures**	**Affiliation**
151	RN Kit Carlson	**1**	North Highlands Dialysis Center
152	RN Pam Stolten	**1**	North Highlands Dialysis Center
153	RN Carlito Villajin	**1**	Greater El Monte Dialysis Center
154	RN Corazon DeJesus	**1**	Greater El Monte Dialysis Center
155	RN Marietta Asumbrado	**1**	Greater El Monte Dialysis Center
156	RN Carolina Chang	**1**	Greater El Monte Dialysis Center
157	RN Glen Hurtig	**1**	Greater El Monte Dialysis Center
158	RN Christine Espino	**1**	Greater El Monte Dialysis Center
159	RN Cynthia DeSagun	**1**	Greater El Monte Dialysis Center
160	RN Fe S. Francisco	**1**	Davita Downey Dialysis Center Downey
161	RN Aida F. Legan	**1**	Davita Downey Dialysis Center Downey
162	RN Rosana Nunez	**1**	Davita Downey Dialysis Center Downey
163	RN Zenaida Butler	**1**	Davita Downey Dialysis Center Downey
164	RN Liberty Hackworth	**1**	Davita Downey Dialysis Center Downey
165	RN Cristina Robles	**1**	Davita Downey Dialysis Center Downey
166	RN Therise Conner	**1**	Redding Dialysis Center Redding
167	RN Paul Goura	**1**	Redding Dialysis Center Redding
168	RN Eva O. Vaughan	**1**	Redding Dialysis Center Redding
169	RN Gloria Dains	**1**	Redding Dialysis Center Redding
170	RN Terri Araiza	**1**	Redding Dialysis Center Redding
171	RN Sandra Vanie	**1**	Redding Dialysis Center Redding
172	RN Rachel Oiler	**1**	Redding Dialysis Center Redding
173	RN Elizabeth Wahl	**1**	Redding Dialysis Center Redding
174	RN Marge Orze	**1**	Redding Dialysis Center Redding
175	RN Shirley Carpenter	**1**	Placerville Dialysis Center Placerville
176	RN Sandra Bach	**1**	Placerville Dialysis Center Placerville
177	RN Susan Mace	**1**	Placerville Dialysis Center Placerville
178	RN Kathy Garcia	**1**	Manzanita and University Peritoneal Dialysis
179	RN Robin Maita	**1**	Davita Regional Office Sacramento
180	RN Alice M. Slutter	**1**	Temecula Dialysis Center Temecula
181	RN Marivic B Malonzo	**1**	Orangevale Dialysis Center Orangevale
182	RN Catherine Ettari	**1**	Davita Mountain Vista
183	RN Jan Kriz	**1**	Davita Hemet San Jacinto
184	RN Barbara Del Fante	**1**	Sunrise Community Dialysis Center
	Total Letters of Support = 184		**Total Signatures = 187**

Hemodialysis Regulations: LETTERS OF OPPOSITION - June 5 through June 20, 2002			
	Name	**Signatures**	**Affiliation**
1	RN JD Hedy Dumpel	**1**	California Nurses Association
2	RN MN Geri Nibbs	**1**	Board of Registered Nursing
3	Dep. Dir. Brenda G. Klutz	**1**	Department of Health Services
4	Leg. Adv. Lydia C. Bourne	**1**	American Nurses Association California
5	RN JD Susan Dawson	**1**	Kaiser Permanente
6	BSN RN CNN CPHQ J. Brown	**1**	A Bay Area Medical Center
7	RN BSN Catherine Kennedy et al	**33**	Kaiser Permanente, Capitol and Central CA
8	RN EdD Dottie Phillips	**1**	Allan Hancock College
9	RN Jerome McCockran et al	**18**	Kaiser Permanente, Oakland
10	RN BSN PHN Pamela M. Luiz	**1**	None noted
11	RN Patricia Barron	**1**	None noted
12	BS RN Karin Kidd	**1**	None noted
13	RN Cindy Biggs	**1**	None noted
14	RN Tyra C. Butler	**1**	None noted
15	RN Ben Woidyla	**1**	None noted
16	RN Mirltia Kaufman	**1**	None noted
17	RN Mary K. Hoggard	**1**	None noted
18	RN Diane Korsears	**1**	None noted
19	RN Wendy Wilson	**1**	None noted
20	RN BSN Leslie Hawkins	**1**	Kaiser Permanente, Central California
21	RN Zenei T. Cortez	**1**	None noted
22	LNP Tami Hoagland	**1**	None noted
23	RN Beverly Elemen	**1**	None noted
24	RNP Kathryn Zender	**1**	None noted
25	RN Trande Phillips	**1**	None noted
26	RN Avis Doherty	**1**	None noted
27	RN Bonnie Martin	**1**	None noted
28	RN MS Patricia Aleshire Briggs	**1**	El Camino Hospital, San Jose
29	NP Valerie Ozsu	**1**	None noted
30	RN Phillip Navarro	**1 form letter**	None noted
31	RN Connie Navarro	**1 form letter**	None noted
32	RN Gilbert D'Souza	**1 form letter**	None noted
33	RN signature undeciferable	**1 form letter**	None noted
34	RN Leslie Neely	**1 form letter**	None noted
35	RN Vanaye Ransom	**1 form letter**	None noted
36	RN Vicki Irwin	**1 form letter**	None noted
37	RN Wendy Brandon	**1 form letter**	None noted
38	RN Stacy Ybana	**1 form letter**	None noted
39	RN Nancy LaPlace	**1 form letter**	None noted
40	RN Lynn Adams	**1 form letter**	None noted
41	RN Marlene Giusti	**1 form letter**	None noted
42	RN signature undeciferable	**1 form letter**	None noted
43	RN signature undeciferable	**1 form letter**	None noted
44	RN signature undeciferable	**1 form letter**	None noted
45	RN Terry last undeciferable	**1 form letter**	None noted
46	RN signature undeciferable	**1 form letter**	None noted
47	RN signature undeciferable	**1 form letter**	None noted
48	RN signature undeciferable	**1 form letter**	None noted
49	RN Mark last undeciferable	**1 form letter**	None noted
50	RN signature undeciferable	**1 form letter**	None noted

Hemodialysis Regulations: LETTERS OF OPPOSITION - June 5 through June 20, 2002			
	Name	**Signatures**	**Affiliation**
51	RN Evelyn M. Torres	**1 form letter**	None noted
52	RN Ludy Vazotz	**1 form letter**	None noted
53	RN Rene Dema-ala	**1 form letter**	None noted
54	RN Noel de Vera	**1 form letter**	None noted
55	RN signature undeciferable	**1 form letter**	None noted
56	RN signature undeciferable	**1 form letter**	None noted
57	RN signature undeciferable	**1 form letter**	None noted
58	RN signature undeciferable	**1 form letter**	None noted
59	RN signature undeciferable	**1 form letter**	None noted
60	RN Kaydee Teh	**1 form letter**	None noted
61	RN Susan Price	**1 form letter**	None noted
62	RN Lolita L. Stanton	**1 form letter**	None noted
63	LVN Gloria E. Batista	**1 form letter**	None noted
64	RN signature undeciferable	**1 form letter**	None noted
65	LVN Rhonda Aguilar	**1 form letter**	None noted
66	RN Linda Bridge	**1 form letter**	None noted
67	RN Rosemarie Oandasan	**1 form letter**	None noted
68	RN Hildegarde D Poriano	**1 form letter**	None noted
69	RN Debbie last undeciferable	**1 form letter**	None noted
70	RN Margaret R Smith	**1 form letter**	None noted
71	RN signature undeciferable	**1 form letter**	None noted
72	RN Nellaflor Manaytag	**1 form letter**	None noted
73	RN signature undeciferable	**1 form letter**	None noted
74	RN Ingrid Spaniol	**1 form letter**	None noted
75	RN Matile Bass	**1 form letter**	None noted
76	RN Tina Cerruti	**1 form letter**	None noted
77	RN Erin Fleishman	**1 form letter**	None noted
78	RN Kathy Carder	**1 form letter**	None noted
79	RN Pamela Bennett	**1 form letter**	None noted
80	RN Karen Rothblatt	**1 form letter**	None noted
	Total Letters of Opposition = 80		**Total Signaures = 129**